



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: July 31, 2014

SUBJECT: NEU1165M Slug and Snail Bait (EPA Symbol #: 67702-3), Containing 0.9% of Complex Polymeric Polyhydroxy Acid (Active Ingredient). Science Review of Product Chemistry, CSF, Label and Toxicity data in Support of Section B680 Registration

Decision Number: 487003
DP Number: 419776
EPA Reg. #: 67702-3
Chemical Class: Biochemical
PC Code: 034903
MRIDs: 49

From: Manying Xue, Chemist
BPB/BPPD (7511P)

A handwritten signature in black ink, appearing to read "Manying Xue", written over a horizontal line.

To: Cheryl Greene, Regulatory Action Leader
BPB/BPPD (7511P)

Action Requested:

On behalf of W. Neudorff GmbH KG's, Walter G Talarek, PC has submitted an application for an amendment of a registered product, NEU1165M Slug and Snail Bait, EPA Reg. No. 67702-3. The registrant requests to revise the product's Confidential Statements of Formula (CSFs) by adding an unregistered source [REDACTED] for the active ingredient of two alternate formulations.

In support of this registration, the registrant has submitted product chemistry data, CSFs (a basic and two alternates), dated 01/10/14, label and waiver request for acute toxicities.

BPPD has examined the submitted data for this amendment. The decisions are made to reflect the current OCSPP policies.

*Product ingredient source information may be
entitled to confidential treatment*

Recommendations and deficiencies are noted below:

- 1a. No CSF for the TGAI from the new source [REDACTED] has been submitted. The CSF for the TGAI from the new source is required.
- 1b. The submitted CSFs, dated 01/10/14 for NEU1165M Slug and Snail Bait are **ACCEPTABLE** for the basic formulation, and **UNACCEPTABLE** for two alternate formulations. The registrant needs to add supplier information in the CSFs for the two alternate formulations. The CSFs will be reevaluated when all of deficiencies for the TAGI from the new source are resolved.
- 1b. The submitted preliminary analysis, enforcement analytical methods, manufacturing process, and formation of impurities for the TGAI from the new source [REDACTED] are **ACCEPTABLE**.
- 1c. The cited study (MRID 4402702) for the storage stability (830.6313) is **UNACCEPTABLE**. The cited storage stability data was for the end use product, NEU1165M Slug and Snail Bait, EPA Reg. No. 67702-3. The data does not support the registration of the TGAI from the new source [REDACTED]
2. The cited toxicity studies for the TGAI from the new source [REDACTED] are **UNACCEPTABLE**. The cited acute toxicity data were for the registration of the end use product, NEU1165M Slug and Snail Bait which do not support the registration of the TGAI from the new source.
3. No non-target organism studies have been submitted for registration of the TGAI from the new source. Non-target organism data are required for this registration.

Background Information and Study Summaries

CERTIFIED LIMITS: The nominal concentration and certified limit for the ingredients of the EP product, NEU1165M Slug and Snail Bait, EPA Reg. No. 67702-3 are listed in Tables 1-3 for the one basic and two alternate Confidential Statements of Formula (CSFs), dated 01/10/14.

The certified limits given for the active ingredient exceed the OCSPP-recommended range ($\pm 14\%$ vs $\pm 10\%$ recommended); and no explanation is provided. The certified limits for the inert ingredients are within their respective OCSPP-recommended guidelines.

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TABLE 1. Nominal concentration and certified limits for NEU1165M Slug and Snail Bait (basic formulation)a					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Iron phosphate (10045-86-0)	034903	Active ingredient	0.97	0.83	1.11
Inert ingredients					

^aData from CSF, dated 01/10/14

TABLE 2. Nominal concentration and certified limits for NEU1165M Slug and Snail Bait (alternate formulation #1) ^a					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Iron phosphate (10045-86-0)	034903	Active ingredient	0.97	0.83	1.11
Inert ingredients					

^aData from CSF, dated 01/10/14

TABLE 3. Nominal concentration and certified limits for NEU1165M Slug and Snail Bait (alternate formulation #2) ^a					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Iron phosphate (10045-86-0)	034903	Active ingredient	0.97	0.83	1.11
Inert ingredients					

^aData from CSF, dated 01/10/14

Inert ingredient information may be entitled to confidential treatment

***Product ingredient source information
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Physical and Chemical Characteristics

The product chemistry data base for the active ingredient, iron phosphate produced by [REDACTED] is essentially complete. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 4.

TABLE 4. Physical and Chemical Properties for Ferric Phosphate ^a			
Guideline Reference No./Property		Description of Result	Methods
830.6302	Color	Off-white	Visual inspection
830.6303	Physical State	Powder	Visual inspection
830.6304	Odor	Odorless	Olfactory inspection
830.6313	Stability	MRIDs 44043702 and 44042703 cited	
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain strong oxidizing or reducing agents	
830.6315	Flammability	Not applicable, the product does not contain flammable liquids	
830.6316	Explosibility	Not applicable, the product does not contain explosive components	
830.6317	Storage Stability	Not required for TGAI	
830.6319	Miscibility	Not applicable, the product is not to be diluted with petroleum solvents	
830.6320	Corrosion Characteristics	Not required for TGAI	
830.6321	Dielectric Breakdown Voltage	Not applicable, the product is not intended for use around electrical equipment	
830.7000	pH	3.0 (1% aqueous solution)	CIPAC MT 75
830.7100	Viscosity	Not applicable, the product is a solid	
830.7200	Melting Range	The active ingredient has no melting point at temperatures up to 500°C	
830.7220	Boiling Range	Not applicable, the product is a solid	
830.7300	Density/Relative Density/Bulk Density	Relative density = 2.69 g/mL at 21°C Pour density = 0.434 g/mL Tap density = 0.574 g/mL	CIPAC MT 159
830.7370	Dissociation Constant in Water	Not applicable, the active ingredient is practically insoluble and does not go into solution	
830.7550	Partition Coefficient	Not applicable, the active ingredient is not organic	
830.7840	Water Solubility	Increases with initial weight 52 mg/kg (~1 g/mL) 218 mg/kg (~5 g/mL)	Not provided
830.7950	Vapor Pressure	3.0 x 10 ⁻⁴ hPa at 20°C 3.6 x 10 ⁻⁴ hPa at 25°C 8.2 x 10 ⁻⁴ hPa at 50°C	Extrapolated from experimental data (vapor pressure balance method)

^aData from MRID 49299803

Storage Stability

Product ingredient source information may be entitled to confidential treatment

The cited storage stability data was for the registration of the end use product, NEU1165M Slug and Snail Bait, EPA Reg. No. 67702-3. The data does not support the registration of the TGAI from the new source [REDACTED]

Enforcement Analytical Method

The enforcement analytical methods used to determine the content of active ingredient are AAS-Flame to determine iron and UV/VIS to determine phosphorous. Details of the methods are provided in MRID 49299802.

Preliminary Analysis

Five-batch analysis for the active ingredient, iron phosphate produced by [REDACTED] is submitted. The results indicates that the average concentration of iron phosphate is determined to be $99.1 \pm 2.3\%$.

The impurities of toxicological concern and water in the same five batches of active ingredient produced by [REDACTED] are analyzed. The registrant states that the concentrations of these impurities are below the maximum allowable for food grade iron phosphate established in the Food Chemicals Index ($<0.0004\%$ for lead, $<0.0003\%$ for arsenic, $<0.005\%$ for fluoride, and $<0.0003\%$ for mercury).

Manufacturing Process

[REDACTED]

Formation of Impurities

[REDACTED]

Quality control process information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

***Product ingredient source
information may be entitled to**

Acute Toxicity Data

The cited toxicity studies (MRIDs: 44042705- 44042707) for the TGAI from the new source [REDACTED] are UNACCEPTABLE. The cited acute toxicity data were for the registration of the end use product, NEU1165M Slug and Snail Bait which do not support the registration of the TGAI from the new source.

Non-Target Organism

No non-target organism studies have been submitted for registration of the TGAI from the new source. Non-target organism data are required for this registration.

cc: C. Greene; BPPD Chron File; OHAD/ARS
M. Xue, BPPD, 07/31/14